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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,027	09/05/2003	Alma L. Burlingame	UCSF04-016-1	8829
23379	7590	03/08/2006	EXAMINER	
RICHARD ARON OSMAN SCIENCE AND TECHNOLOGY LAW GROUP 242 AVE VISTA DEL OCEANO SAN CLEMENTE, CA 92672			MEAH, MOHAMMAD Y	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/657,027	BURLINGAME ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mohammad Meah	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

With preliminary amendment of this application, the applicant, on date 01/30/2006 elected claims 1-2 for examination and claims 3-10 cancelled.

### ***Claim Rejections***

#### **35 U.S.C 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to methods of detecting a post translational modification of any protein comprising detecting O-sulfonation of serine or threonine by using any method. The specification fails to describe in any fashion the physical and/or chemical properties of the claimed class of modified protein and characteristics and definition of the method. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detecting a post translational modification via detecting O-sulfonation of serine or threonine of a protein (such as *Lymnaea stagnalis* protein or *Plasmodium fliciparum* polypeptide, etc) by HPLC/MS/MS (high pressure liquid chromatography/ mass spectrometry/mass spectrometry) or detecting O-sulfonation of serine or threonine of *Lymnaea stagnalis* protein or *Plasmodium fliciparum* polypeptide by immunoassay method (using o-sulfonated serine/ threonine protein specific antibody), does not reasonably provide enablement for any method of detecting a post translational modification of **any protein** comprising detecting O-sulfonation of serine or threonine by using **any method** . The claims broadly recite the use of **any method** for detecting post-translational modification of **any protein** comprising o-sulfonation of serine or threonine residue. The specification describes only two methods of detecting O-sulfonation of a serine or threonine residue of a protein. These are the HPLC/MS/MS method described (pages 11-12 of the specification) and the immunoassay method described (pages 14-17 of the specification). The specification does not teach **any other**

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methods of detecting o-sulfonation yet the claims recite no steps of how o-sulfonation of serine or threonine is detected and thus read on any method. Furthermore the immunoassay method described by applicants cannot be reasonably expected to be useful for detecting O-sulfonation of any protein because immunoassay method based on antibody to a specific protein.

Characteristics of an antibody depend on the structure and function of a protein. As O-sulfonation of serine and/or threonine was a previously unknown post-translational modification of proteins, there are no known methods of detecting this structure nor would other methods be readily apparent to a skilled artisan. The specification fails to describe how any method can detect any such a modified protein. Furthermore, the claimed methods of detection of o-sulfonated serine and/or threonine containing protein likely to include many methods, which one of ordinary skill in the art would be unable to make and use without undue experimentation.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including many methods of detecting post-translational modifications comprising O-sulfonation of serine or threonine of vast numbers of proteins. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, detection of any O-sulfonated serine/threonine containing protein with any method is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

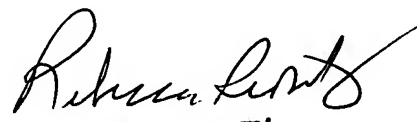
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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